UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/730,856 | 12/08/2003 | Edgar Engleman | 03102.0013.NPUS01 | 3525 |

27194 7590 07/17/2006

HOWREY LLP
C/O IP DOCKETING DEPARTMENT
2941 FAIRVIEW PARK DRIVE, SUITE 200
FALLS CHURCH, VA 22042-2924

| EXAMINER | |
|---|---|
| SCHWADRON, RONALD B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/730,856 | ENGLEMAN, EDGAR | |
| | Examiner | Art Unit | |
| | Ron Schwadron, Ph.D. | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-8 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-8 are under consideration.

2. The rejection of claims 1-6 under 35 U.S.C. 102(e) as being anticipated by Grillo-Lopez (US Patent 6,455,043) for the reasons elaborated in the previous Office Action are withdrawn in view of the amended claims.

3. The rejection of claims 1-7 under 35 U.S.C. 102(e) or (a) as being anticipated by Goldenberg (US Patent 6183744) for the reasons elaborated in the previous Office Action are withdrawn in view of the amended claims.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grillo-Lopez (US Patent 6,455,043) in view of Eichborn et al. (US Patent 5,145,677). Applicants arguments have been considered and deemed not persuasive.

Grillo-Lopez teaches the treatment of Non-Hodgkin's lymphoma with chimeric or humanized monoclonal antibody against CD20 and IFNgamma(see abstract, column 3, second and third paragraph, column 4, first paragraph, column 15, last paragraph continued on column 16 and column 2, last paragraph). Grillo-Lopez teaches use of anti CD20 antibody (Rituximab) at a dosage encompassed by that recited in the claims (see column 8, first paragraph wherein the dosage of 375 mg/m2 is equal to approximately 750 mg for the hypothetical 75 kg person). Grillo-Lopez does not teach the method of claims 7-8 or the time period of IFN-$\gamma$ administration as now recited in claim 1.

Eichborn et al. discloses use of human IFN-γ for the treatment of lymphoma at a dosage encompassed by that recited in claim 8 (see claim 1 and column 4, last paragraph, wherein the average human is about 2 $m^2$ ). Grillo-Lopez teaches the antibody can be administered after therapeutic agent is given (see column 3, paragraphs two and three). A routineer would have determined the time between IFN-γ administration and antibody administration via routine experimentation. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Grillo-Lopez teaches the treatment of Non-Hodgkin's lymphoma with chimeric or humanized monoclonal antibody against CD20 and IFN-γwhilst Eichborn et al. discloses use of human IFN-γ for the treatment of lymphoma at a dosage encompassed by that recited in claim 8, and Grillo-Lopez teaches the antibody can be administered after therapeutic agent is given wherein a routineer would have determined the time between IFN-γ administration and antibody administration via routine experimentation. One of ordinary skill in the art would have been motivated to do the aforementioned because Grillo-Lopez teaches the treatment of Non-Hodgkin's lymphoma with chimeric or humanized monoclonal antibody against CD20 and IFN-γ whilst Eichborn et al. discloses use of human IFN-γ for the treatment of lymphoma at a dosage encompassed by that recited in claim 8.

Regarding applicants comments about Grillo-Lopez, column 16, first incomplete paragraph, said paragraph is a description of a prior art reference, not a method of treatment. It also refers to particular dosages that were used in said prior art reference, not dosages to be administered to a patient. In fact, based on the description of said prior art reference, it appears to refer to in vitro experiments. Grillo-Lopez teaches that routine experimentation would be applied to determine the optimal administration protocol (see column 11, second paragraph). Furthermore, in the case of IFNalpha, Grillo-Lopez discloses data similar to that referred to in the passage quoted by applicant(see column 11, lines 28-30), yet Grillo-Lopez disclose that the IFNalpha was administered for five weeks prior to initiation of antiCD20 antibody (see column 13, lines 25-41).

6. No claim is allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644

RON B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600